

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

FILED
U.S. DISTRICT COURT
BALTIMORE, MARYLAND
2000 NOV 20 P 2:17

WILLIAM COOPER,

Plaintiff,

v.

SMITH & NEPHEW, INC.,

Defendant.

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Civil No. JFM 97-2578

MEMORANDUM

Now pending before the court are two dispositive motions: Defendant Smith & Nephew's Motion to Exclude the Testimony of William Mitchell, M.D., and for Summary Judgment for Lack of Proof of Causation, and Defendant Smith & Nephew's Motion for Summary Judgment Dismissing Claims of the Plaintiff. The facts relevant to the dispute follow.

On January 28, 1990, William M. Cooper ("Cooper") slipped on a patch of ice while working. He complained of lower back and leg pain resulting from the accident. An MRI performed on March 1, 1990 revealed herniated disks between lumbar vertebrae positions 3 and 4 ("L3-L4"), 4 and 5 ("L4-L5") and lumbar position 5 ("L5") and sacral region 1 ("S1"). After undergoing two procedures to alleviate pain, Cooper had a spinal fusion surgery on June 19, 1991. Spinal fusion stabilizes the spine by fusing two or more vertebrae into a single bone. Dr. James C. Murphy ("Dr. Murphy") performed the surgery, during which he inserted the Rogozinski spinal fusion system ("Rogozinski device") between the L3-L4, L4-L5 and L5-S1 vertebrae. The Rogozinski device, a type of spinal fusion instrumentation, uses connectors, rods,

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screws and hooks to support the fusion process. The surgery did not improve Cooper's condition; he continued to complain of back and leg pain after the surgery.

Dr. Murphy believed that nonunion had occurred at each vertebrae level and recommended a second fusion surgery, which he performed on October 15, 1992. The second surgery revealed that fusion had occurred at L3-L4 and L4-L5; he removed the pedicle screws at these levels. Since a nonunion had occurred at the L5-S1 level, however, Dr. Murphy attempted to refuse it. But a CT scan taken eight months after the surgery revealed that a screw had cracked on the left side of S1.

On February 17, 1995, Dr. Murphy performed another surgery on Cooper. He removed the fractured screw at left S1 and again attempted to fuse L5-S1. Dr. Murphy performed the fusion both anteriorly and posteriorly and the operation lasted approximately ten hours. Two days after the surgery Cooper developed adult respiratory distress syndrome ("ARDS"). He was transferred to a critical care unit and placed on a respirator. Despite the complications, the surgery resulted in a fusion at L5-S1.

Cooper brought this lawsuit against Smith & Nephew, Inc. ("Smith & Nephew"), the manufacturer of the Rogozinski device, based on alleged defects. He asserts claims for Fraud, Civil Conspiracy, Concert of Action, Fraudulent Marketing and Promotion, Negligent Misrepresentation, Strict Liability in Tort, Liability Per Se, Negligence and Breach of Implied Warranty of Merchantability. Under Maryland law, in order to prevail on any of these claims, Cooper must show that the Rogozinski device was the proximate cause of his injuries. Maryland Cas. Co. v. Therm-O-Disc, Inc., 137 F.3d 780, 786 (4th Cir. 1998); Lee v. Baxter Healthcare Corp., 721 F. Supp. 89, 95 (D. Md. 1989); Fitzgerald v. Smith & Nephew Richards, Inc., No. 95-

3870, 1999 WL 1489199, at *2 (D. Md. Dec. 30, 1999). In order to show proximate cause in a case concerning medical causation, the plaintiff must present expert testimony. Lee, 721 F. Supp. at 95-96 (finding expert testimony necessary "since the cause of the injury claimed is a technical medical question beyond the common knowledge of laypersons"); Fitzgerald, 1999 WL 1489199, at *2. The defendant challenges Dr. Mitchell's qualifications as an expert and seeks to exclude his testimony as unreliable. If Dr. Mitchell's testimony is excluded, summary judgment is warranted on all of Cooper's claims.

I.

The admissibility of expert testimony is governed by Rule 702 of the Fed. R. Evid., which states:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702. Although Smith & Nephew claims that Dr. Mitchell should not be qualified as an expert in spinal fusion with instrumentation, I will assume for present purposes that Dr. Mitchell is qualified as an expert in order to address the admissibility of his testimony.

Expert testimony is admissible if it is reliable and relevant. Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579, 589 (1993); Westberry v. Gislaved Gummi AB, 178 F.3d 257, 260 (4th Cir. 1999). The reliability prong requires a court to evaluate "whether the reasoning or methodology underlying the expert's proffered opinion is reliable - - that is, whether it is supported by adequate validation to render it trustworthy." Westberry, 178 F.3d at 260. Daubert mandates a flexible inquiry into the expert's methodology and does not require that the expert's

final opinion be "irrefutable or certainly correct." Id. at 261.

Nonetheless, I find that Dr. Mitchell's testimony is unreliable.¹ His method is almost wholly conclusory. Dr. Mitchell, who has never performed a spinal fusion with instrumentation, asserts that the Rogozinski device must achieve a spinal fusion; if it fails, *ipso facto*, there was a defect and it caused whatever injuries follow. During his deposition, defense counsel questioned Dr. Mitchell: "Purely retrospective[ly] looking back, [Cooper] didn't get a fusion, the screw broke, therefore it's defective; right?" Dr. Mitchell responded, "Right." Mitchell Dep. at 70. Later, the following exchanged occurred:

Q. Let's assume in patient A we do not get a fusion, one of the screws loosens and breaks. Okay?

A. Right.

Q. Let's assume in patient B we get a fusion and there's no loosening and no breakage of the screw.

Now, in your opinion the Rogozinski device in patient A would be defective?

A. Right.

Q. But the Rogozinski device in patient B would not be defective; right?

A. Correct.

Mitchell Dep. at 118-19. Dr. Mitchell does not probe or explain the factual chain warranting this ultimate conclusion.

Indeed, it is not easy to define the defect to which Dr. Mitchell attempts to link Cooper's

¹I hardly decide this question in a vacuum. I note at the outset that numerous courts have excluded Dr. Mitchell's testimony as unreliable in similar "bonescrew" lawsuits. See, e.g., Baker v. Smith & Nephew Richards, Inc., No. 1:97-CV-1233, 1999 WL 1129650, at *4-5 (N.D. Ga. Sept. 30, 1999); Jones v. Sofamor SNC, No. 1:96-CV-3167, 1999 WL 1062103, at *3 (N.D. Ga. Apr. 29, 1999); Conger v. Danek Medical, Inc., No. 96-CV-739-A, 1998 WL 1041331, at *5 (N.D. Tex. Dec. 14, 1998); Cali v. Danek Medical, Inc., 24 F. Supp. 2d 941, 951 (W.D. Wis. 1998); cf. Driggers v. Sofamor SNC, 44 F. Supp. 2d 760, 764-65 (M.D.N.C. 1998) (Dr. Mitchell's testimony regarding causation not enough to survive summary judgment for defendant).

injuries. Dr. Mitchell's report first asserts that defects were manifest in the June 19, 1991 operation. Mem. Supp. Def. Smith & Nephew's Mot. to Exclude Test. of William Mitchell, M.D. ("Def.'s Mem.") Ex. A. Yet, the Rogozinski device successfully fused the L3-L4 and L4-L5 vertebrae as a result of the first surgery. Although a nonunion resulted at L5-S1, Dr. Mitchell points to no evidence suggesting a crack of the left screw at L5-S1 until the June 15, 1993 CT scan (after the second surgery on October 15, 1992).² Def.'s Mem. Ex. A. Dr. Mitchell's assertion that Cooper's injuries resulted from a defect connected with rods and screws inserted on June 19, 1991 appears to rest on nothing but conclusory assertions.

To the extent that Dr. Mitchell claims that defects in the Rogozinski device arose after the October 15, 1992 surgery, his methodology is similarly suspect. The October 15, 1992 surgery revealed that the L3-L4 and L4-L5 vertebrae had fused. Accordingly, this surgery focused on the L5-S1 vertebrae, where a Rogozinski screw at left S1 eventually fractured, necessitating a third (and complicated) surgery. Cooper claims that this fracture caused nonunion; Smith & Nephew claims nonunion preceded (and caused) the screw's fracture. Instead of focusing on the medical evidence as reported in Cooper's voluminous medical records, Dr. Mitchell seems to infer causation from nonunion alone. Dr. Mitchell's report states summarily: "It is not the job of the bones to heal so that the spinal instrumentation system can remain intact and non-broken. It is the job of the spinal instrumentation system to remain rigid and unbroken." Def.'s Mem. Ex. A. He does not address even supporting evidence that the L5-S1 vertebrae was fusing before the screw fractured and that the screw's resulting fracture caused

²Apparently there was evidence that the right S1 screw had loosened by May 5, 1992. Def.'s Mem. Ex. C. This was not the same screw that ultimately fractured.

nonunion. Dr. Murphy's May 4, 1993 notes, for example, indicate that fusion was occurring after the second operation. Def.'s Mem. Ex. C. Not until June 15, 1993 did a CT scan reveal a fracture at L5-S1.³ Id.

Nor does Dr. Mitchell address facts rebutting the inference that nonunion followed from the screw's fracture. See In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 758 n.27 (3d Cir. 1994) (stating "where a defendant points to a plausible alternative cause and the doctor offers no explanation for why he or she has concluded that was not the sole cause, that doctor's methodology is unreliable"). He summarily rejects evidence that Cooper's long history of smoking caused nonunion, even though Cooper's medical records contain repeated references to Cooper's smoking habit.⁴ Moreover, the defendants submitted medical journal articles connecting rates of nonunion to smoking. Def.'s Mem. Ex. O. Dr. Mitchell's reaction to these is terse at best. Dr. Mitchell read two articles two or three years ago claiming a causal connection between smoking and nonfusion. Mitchell Dep. at 87-89. He stated, "I wasn't impressed with either of them, so I haven't looked for any more cases of smoking." Mitchell Dep. at 89. Asked if he should have considered other articles contradicting his position, Dr. Mitchell replied:

No, for the simple reason, after I read those two articles years ago, they didn't affect my prior judgment, and they still haven't, that smoking doesn't have anything to do with healing in spinal fusion. So even if there were ten more articles, I'm not going to change

³There is a potential inconsistency in Dr. Murphy's notes. In his June 15, 1993 notes, Dr. Murphy indicated that the L5-S1 screw "was broken in May." Def.'s Mem. Ex. C. His May 4, 1993 notes indicate that fusion was occurring. Id. Dr. Mitchell's failure to address this issue reveals that his conclusions generally do not rest on evidentiary details.

⁴The plaintiff argues that successful fusions at L3-L4 and L4-L5 rebut the argument that Cooper's smoking habit caused the nonunion at L5-S1. Dr. Mitchell offers no expert testimony on this point.

my mind about it.


Mitchell Dep. at 162. Dr. Mitchell's responses to other questions positing causal factors for injuries that Cooper attributes to the L5-S1 nonunion are similarly cursory. Mitchell Dep. at 130-51.

Dr. Mitchell's report and deposition indicate that he simply disagrees with spinal fusion with instrumentation as a surgical option; his testimony does little to explain how and why an (allegedly) defective device caused a particular patient's injuries. Accordingly, I exclude as unreliable Dr. Mitchell's testimony on medical causation. Because all of Cooper's claims require expert medical testimony, Smith & Nephew's motion for summary judgment on all of Cooper's claims is granted.⁵

An order effecting this ruling will be entered herewith.

Date:

November 20, 2000



J. Frederick Motz
United States District Judge

⁵Because the summary judgment motion with respect to Dr. Mitchell's testimony and causation is dispositive, I do not address Smith & Nephew's other pending motion for summary judgment.